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| EXAMINER |
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1634

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/744,675 | | SQUIRES ET AL. | |
| | Examiner | | Art Unit | |
| | Carla Myers | | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 138-145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 138-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed November 1, 2006. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Claims 138-145 are pending and have been examined herein.

Information Disclosure Statement

2. In the information disclosure statement filed in this application on November 1, 2006, the citations to Ozhin, Prokofiev, Solsberry, Wintzer and van Munster have not been considered by the examiner and have been lined through. In the response, Applicant included a statement that Ozhin "may include disclosure relative to artificial insemination of farm animals;" Prokofiev "was cited in an application that may involve technology relevant to that of the instant application;" Solsberry "may include disclosure relative to artificial insemination of cows;" Wintzer "may include disclosure relative to artificial insemination;" and van Munster "may include disclosure relative to sex determination with interferometry." However, these vague statements of what the documents "may" disclose do not provide a sufficient explanation of the relevance of each of the cited non-English documents. An explanation of what the documents do in fact disclose is required, as set forth in MPEP 609.

Further, the citations to "Milk Production and Biosynthesis" and "Managing the Dairy Cow During the Dry Period" have not been considered and have been lined through because a publication date for these references was not provided.

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The citation to the foreign patent document UK 1471019, 4/21/1977 has not been considered and has been lined through because a copy of this document was not provided.

The other items of information that are otherwise in compliance with the provisions of 37 CFR §1.97-1.98 have been considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on November 1, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Application No. 09/582,809 and 10/081,955 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The Following are New Grounds of Rejection Necessitated by Applicant's Amendments to the Claims:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 138-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The specification as originally filed does not appear to provide support for the claimed methods of establishing an equine artificial insemination sample containing at least some sperm that are capable of fertilizing at least one egg within a female equine "at success levels selected from the group consisting of at least 87%, 70%, 53%, and 18% as compared to an unsorted insemination dosage of about the same number of sperm cells.

In the response filed November 1, 2006, applicants assert that support for this amendment may be found in Table 1, page 33 and in Table 2, page 38. It is stated that these tables illustrate two trials in which "equal numbers of sperm" were used for unsorted and sorted inseminations. Pregnancy rates of 57% for 25×10^6 unsorted sperm and 50%, 40%, 30% and 10% for sorted sperm were obtained. Applicants conclude that these teachings provide support for methods in which the success levels are at least 87%, 70%, 53%, and 18% as compared to an unsorted insemination dosage of about the same number of sperm cells.

However, these teachings in the specification establish the results obtained when comparing artificial insemination samples containing "equal numbers of" sorted and unsorted sperm. These teachings do not provide support for the amendment in which the success level is set forth in terms of a comparison between sorted equine artificial insemination dosages and unsorted equine artificial insemination dosages "containing about the same number of sperm cells." The specification does not define what constitutes "about the same number of sperm cells" and does not provide support for

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the amendment to compare results obtained with samples containing "about the same number of sperm cells."

Further, the teachings in the specification establish success levels at 87.7% (i.e., 50% versus 57%), 70.2% (40% versus 57%), 52.6% (30% versus 57%) and 17.5% (10% versus 57%). These teachings do not provide support for the broader concepts of success levels that are at least 87%, 70%, 53%, and 18% as compared to an unsorted insemination dosage. For example, an example in which the success level using sorted sperm was 87.7% as compared to unsorted sperm does not provide support for a success level of 89%...92%...100% as encompassed by the present claim language of "at least".

Maintained Rejections

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 138-140, and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath (Theriogenology. April 1997, 795-800; cited in the IDS).

Rens teaches a method of high speed flow cytometry for sorting sperm. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoeschst 33342 dye in order to distinguish between viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Approximately 50% of the sperm were viable and the sorting was performed at sampling rates of 500 sperm/sec and 2000 sperm/sec (see column 6). Further, the nozzle allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens exemplifies using the claimed sorting method using rabbit, bull, mouse and human sperm (columns 4-7) and states that the sorting method can be used with any mammalian sperm (column 4, lines 38-42). Rens does not specifically exemplify applying the sorting method to equine sperm.

However, Wilhelm teaches the use of equine sperm for the purpose of artificial insemination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine.

Secondly, Rens does not specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath

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teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Rens in which the equine sperm is collected into a media containing egg yolk and skim milk that the sample contains at least one viable sperm cell that is capable of fertilizing at least one equine egg at a level of at least 18% that of a typical unsorted equine artificial insemination dosage.

With respect to claim 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 143, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To determine the optimum conditions for performing the sorting of sperm, including the sorting rates and pressure of the cell sorter is considered to be well within the skill of the

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art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to claims 144 and 145, Rens teaches that 4 to 5 million sorted sperm were used to inseminate dairy cows, but does not teach the quantity and volume of sperm in equine artificial insemination samples. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of

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samples to be used for insemination, and the type of insemination technique.

Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response filed November 1, 2006, Applicants traversed the rejection over Rens in view of Wilhelm and Rath by arguing that Rens does not teach the sorting rates of the present invention. Applicants state that the sampling rates of Rens that were suggested in the previous Office action are in error. It is stated that additional factors influence sampling rates, such as coincidence rates, and therefore "it simply cannot be inferred what Rens' true sorting rate was." This argument has been fully considered but is not persuasive. It is unclear as to how Applicants can assert that Rens does not teach separation rates equivalent to the claimed separation rates if Applicant believes that one cannot ascertain what separation rates were employed by Rens. Applicants present specification appears to rely on the apparatus of Rens and similar apparatuses known in the prior art at the time the invention was made in order to achieve the separation of equine sperm at rates of at least 900 sperm per second. Yet, it remains unclear as to why Applicants believe that they have achieved improved separation rates over Rens when they are unable to provide information regarding the separation rates of Rens.

The response makes several assumptions regarding what they believe the separation rates may be in the method of Rens. Such assumptions are based on the teachings of Johnson in U.S. Patent No. 5,135,759. Applicants conclude that based on their inferences, the sorting rate of Rens is well below that of Applicants. However, Applicants do not provide any declaratory evidence to substantiate their allegations. Applicants' opinions and allegations cannot substitute for declaratory evidence. At page 10 of the response, Applicants themselves acknowledge that "the above calculations are not presented in an attempt to establish what Rens' actual sorting rate was. As has been noted earlier in this and prior communications to the Office, Rens' true sorting rate cannot be accurately inferred without explicit data from Rens that establishes this fact." Applicants assert that the obviousness rejection cannot be maintained without a teaching in Rens of specific sorting rates. This argument is not persuasive because following the methodology of Rens for using the sorting apparatus would result in a method in which particular sorting rates would be achieved. Applicants have not provided any type of declaratory evidence to establish that the method of Rens would not allow for the separation of sperm at rates equivalent to those claimed. Additionally, no persuasive arguments have been provided as to why the use of sorting rates of 900 viable equine sperm cells per second would not have been obvious. As discussed above, to determine the optimum conditions for performing a method step, including the step of separating the sperm, is considered to be well within the skill of the art. Again, the present specification relies on the apparatuses disclosed in the prior art in order to

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achieve the sampling rates set forth in the claims. Applicants have not disclosed any means for increasing the sorting rate of sperm above that disclosed by Rens.

The response argues that Rens does not provide any data on rates of successful fertilization achieved using the sorted sperm. Applicants state that it is the Office's burden to establish the success rates achieved by Rens. This argument has also been considered but is not persuasive. The fertilization success rates are a property/result of the disclosed method. Since the method steps resulting from the combination of teachings of Rens, Wilhelm and Rath are identical to those set forth in the present claims, in the absence of evidence to the contrary, the fertilization success levels achieved by this method are considered to be equivalent to those of the present invention. Again, no evidence has been provided to substantiate the assertion that the method of Rens in view of Wilhelm and Rath does not achieve fertilization rates of at least 18% of that achieved using an unsorted equine sperm dosage of about the same number sperm. Further, Applicants do not point to any particular limitations that are recited in the claims which distinguish the claims over the sorting method of Rens and which would thereby result in the asserted difference in technique and success rates.

As set forth in the MPEP 716.02, the burden is placed on Applicant to establish that "the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). There must be a **clear nexus** between the asserted unexpected results and the method steps that allow for the unexpected results. **Further, the claims**

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must be commensurate in scope with the aspects of the invention which allow for the asserted unexpected results.

However, in the present situation, high sorting rates, including 900 sorts per second, are suggested by the teachings of Rens. **The claims do not recite any particular properties of the sorting apparatus which would distinguish the claimed sorting technique over that of Rens.** The response does not establish a clear nexus between the claims as they are broadly written and any asserted unexpected results. For instance, there is no showing that sorting equine sperm at any rate of 900 or above (1000, 2000, 10,000, 20,000 sperm/sec etc) using any apparatus, any sheath fluid, any collection device, any quantity of sperm etc can be used to achieve fertilization rates of at least 87% -18% of a typical unsorted insemination dosage. It has also not been established that it is unexpected that one could obtain by high speed sorting an artificial insemination sample containing at least some viable equine sperm cells which have a fertilization level of at least 18% that of a typical unsorted equine artificial insemination dosage.

The specification does not provide any clear teachings as to which aspects of the claimed invention are essential and account for the asserted unexpected results. Throughout the specification there are statements indicating that a particular feature may be important alone or in combination in determining the success of the artificial insemination method. However, the statements are vague and are not accompanied by any factual data. For instance, at page 6 the specification states that "the solutions proposed may to some degree involve a combination of factors which, when thoroughly

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statistically studied, will be shown to be necessary either in isolation or in combination with other factors. Such a determination is further compounded by the fact that the results themselves vary by species and may be difficult to ascertain due to the fact that testing and statistical sampling on a large enough data base is not likely to be worth the effort at the initial stages." Regarding high speed flow sorting, the specification (page 18) states that "(w)ith advances it is anticipated that the percent of sperm that are oriented properly as the droplets pass the laser can increase, resulting in increased sorting rates from 100 live sperm/s of each sex to rates between 1000 and 1500 live sperm/s of each sex at ~90%." However, the specification does not provide any specific details as to the advances which allow for this improved sorting and the response does not point to any particular limitations recited in the claims which allow for the increased sorting rate while maintaining the ability of the sperm to fertilize oocytes at the claimed success rates. Accordingly, for the reasons set forth above, Applicants assertion of unexpected results and improved sorting rates and fertilization rates over those achieved by the method Rens in view of Wilhelm and Rath are not persuasive because the assertion is not accompanied by any factual evidence and there is no showing of a clear nexus between the asserted unexpected results and the claims as they are broadly written.

6. Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and Rath and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens, Wilhelm and Rath are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium. Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid because Catt teaches that this is a suitable dilution medium for sperm and thereby using HEPES-buffered medium as the sheath fluid would have achieved the benefit of ensuring the viability and motility of the sperm.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed this rejection for the same reasons as stated above. Accordingly, the response to those arguments as presented above apply equally to the present grounds of rejection.

7. Claims 138-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (U.S. Patent No. 6,149,867) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might

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be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Seidel teaches a method of high speed flow cytometry for sorting equine sperm. The method of Seidel comprises obtaining a sample of sperm from a male mammal, staining the sperm in order to distinguish between viable and nonviable sperm, sorting the speed using a high speed flow cytometer having a nozzle that forms a stable droplet containing each individual sperm cell wherein the sperm are sorted according to their sex characteristics and isolating populations of X- and Y-chromosome bearing sperm are collected (see column 6). Seidel (column 7) teaches sorting at rates of greater than 500 sorts per second and up to 1000 to 1200 sorts per second. The reference also teaches operating the flow cytometer at pressures of about 50 lbs per square inch

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(column 7). Seidel teaches that when sorting equine sperm, the preferred sheath fluid contains HEPES buffer (column 9).

Seidel teaches that "it has been known to place an initial collector fluid (17) in the bottom of the container to collect the cells so that they do not hit the bottom of the container" (column 10). Seidel states that the collector fluid "may serve to minimize chemical stresses upon the cells. In one regard, since it may be important to provide a nutrient to the cells both before and after sorting, the collector fluid (17) may be selected so as to provide a coordinated level of nutrient so that the levels are balanced both before and after sorting" (column 10). The reference teaches that an egg yolk solution may be used as the collection fluid and that the collection fluid may be chosen so that it is similar to the starting fluid environment or any other fluid environment used in the method (column 11). It is also stated that that the levels of egg yolk may be varied "as those skilled in the art readily understand" (column 11).

Seidel does not specifically teach using a collection fluid that contains skim milk. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

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Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Seidel in which the sperm is collected into a media containing egg yolk and skim milk that the sample contains at least one viable sperm cell that is capable of fertilizing at least one equine egg at a level of at least 30% that of a typical unsorted equine artificial insemination dosage.

With respect to claims 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, as taught by Seidel, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most

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effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claims 144 and 145, Seidel (column 12) teaches using a low dose of sperm for artificial insemination and teaches concentrating bovine sperm to a level of 3-5 million sperm cells per ml (column 13), but does not teach the quantity and volume of sperm in an equine artificial insemination sample. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately $3.5 \text{ to } 4 \times 10^5$ sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique.

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Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response, Applicants state that the 103 rejection has been overcome by the filing of a 132 declaration to establish "the subject matter of the present application prior to the effective filing date of the Seidel reference."

However, the 132 declaration of George Seidel, filed November 1, 2006 is not sufficient to antedate the '867 patent. In particular, a declaration filed under 37 CFR 1.132 may not be used to show possession of a claimed invention prior to the date of an applied reference. Applicants attention is directed to MPEP 715 regarding the filing of a declaration under 37 CFR 1.131 to establish that Applicants were in possession of claimed subject matter prior to the effective date of a reference.

The declaration of George Seidel is also not effective because it does not establish that the acts relied upon to establish the date prior to the reference were carried out in this country or in a NAFTA country or WTO member country. See MPEP 715.

Further, the declaration is not sufficient because it has not been signed by each of the inventors of the present application since declarations that are being made to establish possession of the claimed subject matter prior to the effective date of a

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reference must be signed by each of the inventors. As stated in the MPEP at 715.04, "(a)n affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection." In the present situation, it has not been established that the inventor George Seidel alone is the sole inventor of the **claims** under rejection.

Lastly, the scope of the declaration is not commensurate with the scope of the claimed invention. The declaration states that the declarant "was in possession of the subject matter of claim 138 (g), of the Present application." In particular, the declaration points to Exhibit C as showing that Dr. Seidel was in possession of a method in which sperm are sorted at rates of greater than about 500 sorts per second and that sorting may be performed at rates in the thousands and twelve hundred ranges. However, a declaration seeking to establish an earlier effective filing date must establish possession of either the whole invention claimed or something falling within the claim. Where the differences between the claimed invention and the disclosure of the references are so small as to render the claims obvious over the reference, an affidavit or declaration under 37 CFR 1.131 is required to show no more than the reference shows. In the present situation, the '867 patent is not limited to teaching only step (g) of present claim 138. Accordingly, the declaration is not sufficient because the declaration does not establish that applicants were in possession of each of the method steps of the claimed

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invention or each of the method steps set forth in the '867 patent, prior to the effective filing date of the '867 patent.

The present Declaration of George Seidel does not establish that the subject matter of the presently rejected claims which is also disclosed in the 6,149,867 patent is applicant's own invention. Rather, the declaration establishes that one day prior to the filing date of the '867 patent each of the inventors of the '867 patent, i.e., George Seidel, Lisa Herickhoff and John Schenk, filed a patent application containing the subject matter of the '867 patent. The declaration does not establish that the inventors of the present application, George Seidel, Edward Squires and Patrick McCue, were in possession of the claimed subject matter **which corresponds to subject matter disclosed in the '867 patent** (i.e., the additional subject matter disclosed in the '867 patent which extends beyond the subject matter of claim 138 step (g)).

Applicants attention is drawn to MPEP 715, set forth in part below (emphasis added):

37 CFR 1.131. Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, **may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.** The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). **Prior invention may not be established under this section in any country other than the United**

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States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. ...

(b) The **showing of facts shall be such, in character and weight**, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

Further, the MPEP 715.01 teaches that:

715.01 37 CFR 1.131 Affidavits Versus 37 CFR 1.132 Affidavits

The purpose of a 37 CFR 1.131 affidavit or declaration is to overcome a prior art rejection by proving invention of the claimed subject matter by applicant prior to the

effective date of the reference or activity relied upon in the rejection.

In some situations, an applicant may, alternatively, be able to overcome prior art rejections relying on references or activities which are available as prior art under 35 U.S.C. 102(a) or references which are available as **prior art under 35 U.S.C. 102(e) by proving that the subject matter relied upon in the reference or activity was applicant's own invention.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

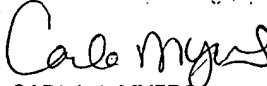
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carla Myers

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CARLA J. MYERS
PRIMARY EXAMINER